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Review Article

Development of pulse diagnostic devices in Korea

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ABSTRACT

In Korean medicine, pulse diagnosis is one of the important methods for determining the health status of a patient. For over 40 years, electromechanical pulse diagnostic devices have been developed to objectify and quantify pulse diagnoses. In this paper, we review previous research and development for pulse diagnostic devices according to various fields of study: demand analysis and current phase, literature studies, sensors, actuators, systems, physical quantity studies, clinical studies, and the U-health system. We point out some confusing issues that have been naively accepted without strict verification: original pressure pulse waveform and derivative pressure pulse waveform, pressure signals and other signal types, and minutely controlled pressure exertion issues. We then consider some technical and clinical issues to achieve the development of a pulse diagnostic device that is appropriate both technically and in terms of Korean medicine. We hope to show the history of pulse diagnostic device research in Korea and propose a proper method to research and develop these devices.

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1. Introduction

Pulse diagnosis is a palpation method that is one of the four diagnostic examinations of Korean medicine. It is a diagnostic method in which a doctor uses finger sensations to observe the pressure pulse waveform (PPW). Korean medical doctors consider this PPW information to understand a patient's health condition or validate medical treatment. In the early days, doctors sensed PPWs at various sites over the whole body, but this has changed to the wrist pulse-taking method. Pulse diagnosis has very high diagnostic importance and significance in Korean medicine, but it depends on a doctor's subjective sensations and oral tradition. To overcome these issues,

many studies have been conducted on the objectification and quantification of pulse diagnosis, and electromechanical pulse diagnostic devices have been invented.

The first wrist pulse diagnostic device was developed in 1968, by Dr. Bong-Kyo Lee, with the opening of Kyung Hee University Oriental Medicine Hospital. Many studies were then conducted on the PPW-generating mechanism, the physical meaning of the PPW, electromechanical sensors, pulse diagnostic device systems, database management systems, and clinical trials. However, the low reliability and controversial validity resulting from the limitations of sensors and actuators, and the lack of understanding among Korean medical doctors, made clinical utilization of the devices very low. Nowadays, engineering techniques and applications have

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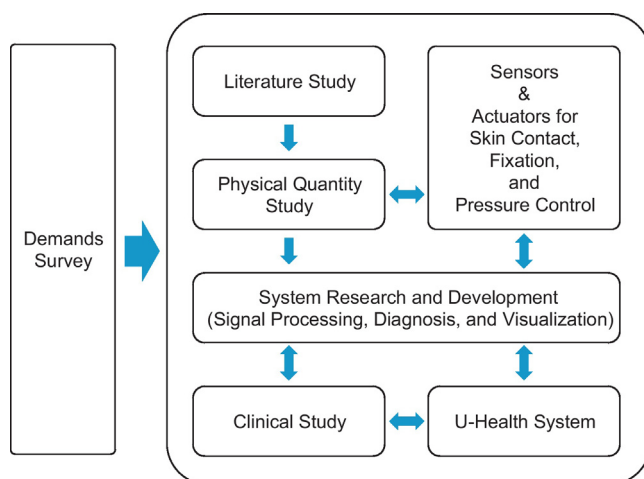


Fig. 1 – Brief diagram of study flow in research and development for pulse diagnostic devices.

seen very rapid advances, so sensors and actuators have become highly developed, and Korean medical doctors' understanding of the objectification and quantification of clinical data has greatly improved. Under these conditions, the need for reliable pulse diagnostic devices has become prominent.

However, there have been few reviews on the objectification of the pulse diagnosis in Korea, even though many studies have been conducted on this issue. Thus, in this paper, we review previous studies on pulse diagnostic devices to discuss present trends and some issues that should be resolved. Section 2 reviews previous studies in many related fields. We then discuss some technical and clinical issues in Section 3. Conclusions are drawn in Section 4.

Studies on pulse diagnosis include photoplethysmography (PPG) and pulse wave velocity (PWV) research in a broad sense. Strictly speaking, however, they are not "wrist PPW studies". Thus, PPG and PWV research and developments related to PPG and PWV have been excluded from this paper.

2. Overview of research and development of pulse diagnostic devices in Korea

Fig. 1 shows a brief diagram that expresses the study flow of research and development for pulse diagnostic devices. In Section 2, we review each stage of the flowchart.

2.1. Demand analysis and current phase

According to a research survey in 2009, 159 Korean medical doctors showed a neutral attitude toward the importance of pulse diagnostic devices,¹ whereas 121 Chinese medical doctors showed a positive response.² In a 2010 survey, 105 Korean medical doctors still showed a neutral attitude.³ The surveys reported common problems with the reliability and validity of the devices. In another study in 2009, only 13% of the respondents said that they used pulse diagnostic devices in their clinics.⁴

Although pulse diagnosis using pulse diagnostic devices is supported by Korea's national insurance scheme, the number of pulse diagnostic devices in use decreased from 3055 in 2002 to 1010 in 2010.⁵ Despite inclusion of the approach in the national insurance scheme and the increase in the number of Korean medical clinics, this decrease in usage means that current commercially available devices cannot provide clinical support and economic benefit.

2.2. Literature studies

Literature reviews on pulse diagnosis have mainly involved translation and interpretation. In particular, medical historical reviews have discussed 12 meridian pulse-taking methods, three position and nine indicator pulse-taking methods, and carotid and wrist pulse-taking methods.⁶⁻¹⁰ Studies have been conducted on the definitions and positioning of *chon*, *guan*, and *cheok* [*cun*, *guan*, and *chi* in the World Health Organization (WHO) international standard terminologies on traditional medicine in the western Pacific region], studies on matching viscera and bowels to *chon*, *guan*, and *cheok*,¹¹⁻¹⁶ and Korean medical physiologic and pathologic studies on specific PPWs.¹⁷⁻²⁰ The reinterpretation and English translation of pulse diagnosis sections of the *Nan Jing* using WHO international standard terminologies for traditional medicine in the western Pacific region have been reported.²¹⁻²³ However, these studies cannot be applied in clinics without strict verification because they mainly focused on the translation and interpretation of the classics, as noted above, and they cite abstract expressions of the traditional medical classics repeatedly and in circular fashion.

The other stream involves studies of the description and classification of the PPW,²⁴⁻²⁹ this is reviewed in detail in Section 2.4 with the physical quantity studies. This area is very important to the research and development of pulse diagnostic devices because these studies can provide many important clues to the physical attributes of the PPW detected by the devices. However, the classics describe the PPW mainly in metaphorical, symbolic, and poetic ways.³⁰ Thus, to modernize pulse diagnosis, the PPW should be studied according to scientific and analytic methodologies.

2.3. Sensors, actuators, and systems

The structure of wrist pulse diagnostic devices is divided into the sensor, the skin contact and pressure-controlling part, the signal-processing part, and the visualization part. In this paper, we focus on the first two because the latter two use a wristband-type embedded system or personal computer system.

2.3.1. Sensors

Sensors are very important because they are the core modules which pick up and quantify the PPW signal. In particular, the physical fundamentals and form characteristics directly influence the methodology used to analyze the PPW and play a definite role in studies on reliability and validity.

Pulse diagnostic devices in Korea have used piezoelectric devices,³¹⁻³³ piezoresistive strain gauges,³⁴⁻³⁷ air-vibration-detecting condenser microphones,^{38,39} optical fiber

Table 1 – Direct measured physical parameters according to sensor type.

Sensor type	Measured physical parameter
Piezoelectric device	Pressure (derivative function)
Piezoresistive strain gauge	Pressure
Condenser microphone	Air vibration
Optical fiber transducer	Displacement
Optical coherence tomography device	Displacement
Fiber Bragg grating	Displacement
Magnetic junction element	Displacement
Magnetic Hall device	Displacement
Moving pulse image	Displacement

transducers that use the reflective optical power change according to infinitesimal displacement,⁴⁰ optical fiber coupling controlled by infinitesimal displacement,^{41,42} optical coherence tomography devices using in-line Michelson interferometers,^{43–46} fiber Bragg gratings,⁴⁷ magnetic junction elements,⁴⁸ magnetic Hall devices,^{49–55} moving pulse images,^{56,57} and so on.

The physical fundamentals of the sensors determine the dimensions of the measured signal. Some sensors detect the original PPW, whereas others detect the derivative of the original PPW. This derivative PPW gives the change rates of the pressure pulse directly but does not reveal anything about the original PPW.^{30,58} In other cases, because the measured data reflect an indirect or partial physical quantity of the PPW, the signal should be transformed to the original PPW through strict physical calculations. Some examples include the condenser microphone, optical fiber transducer, and magnetic junction element. Recently, piezoresistive strain gauges and magnetic Hall devices have been used in the pulse diagnostic devices, and a system with a piezoelectric film sensor and conductive textile has been reported.³³ Table 1 lists directly measured physical parameters according to the sensor types.

2.3.2. Actuators for skin contact, fixation, and pressure control

Actuators for skin contact, fixation, and pressure control are also very important because only correct and firm fixation can guarantee the reliability of the devices. In addition, pressure must be applied perpendicular to the artery in the tonometric pressure measurement system. If not, the perturbation can drive fluctuation of the signal, and the measured data will not reflect the correct PPW.

The pressure-exerting system must be quantified and controlled correctly. In Korean medicine, pulse diagnosis does not mean pulse palpation at the skin surface without pressure, but the sensation of the PPW response to various pressures exerted by the doctor's fingertips. Early pulse diagnostic device models did not include the concept of minutely controlled applications of pressure,⁵⁹ but as the importance of the exerted pressure became highly emphasized, pressure control systems with air-pressure control^{60,61} or a robotic arm⁶² were developed. These systems have been used in basic measurement studies according to the exerted pressure,^{63,64} hemodynamic studies,^{65,66} pressure control method studies,^{67–69} and research into pressure training

systems.⁷⁰ Patents relating to the skin contact, fixation, and pressure control system are continuously being filed.⁴

2.3.3. Pulse diagnosis systems

The first pulse diagnosis system in Korea was the Bong-Kyo type, which was invented in 1968 by Dr. Bong-Kyo Lee using one piezoelectric sensor; he uncovered major features of eight basic pulses by clinical research conducted using this system. The system measured the derivative PPW. Fixation was performed with wristbands, and it was impossible to quantify the exerted pressure. This model was not meant for commercial use, but it was the first approach that reflected the basic theories of Korean and Western medicine and reported clinical meanings.^{38,58}

In 1972, Hee-Soo Paek announced that the experimental model of the Hee-Soo type pulse diagnostic device would go on the market. The Hee-Soo type device at first used piezoelectric sensors, which were then changed to condenser microphone sensors. It could exert pressure with a cuff, but quantification and control of the exerted pressure were still impossible. Measured data from the Hee-Soo-type model were repeatedly differentiated and integrated by the numerical method through signal-processing, so there was a great deal of data loss in the results, which was a critical defect. Thus, controversy over the validity—that is, whether or not the signal from the condenser microphone was a reflection of the radial artery PPW—was the main problem of the Hee-Soo-type model.^{30,38,39,58}

In 1986, Sord Medicom Company developed the Sord-type pulse diagnostic device. Three-channel piezoelectric sensors were used in the Sord-type device, which was based on the Bong-Kyo-type model. First, a fixed sensing part was used; afterward, a glove with sensors in its fingertips was developed. The device was still limited by the derivative PPW and an inability to quantify the exerted pressure.^{30,38,58} In the late 1990s, Dr. Young-Bae Park of Kyung Hee University Oriental Medical Hospital used a piezoresistive strain gauge to overcome the limitation of the derivative PPW,^{34,36,71–73} afterward, this model was developed into a system detecting the pulse–respiration ratio, in which the pulse and respiration signal were considered together to understand a patient's health state.^{24,74–76}

With the start of the new millennium, a brand-new model using array strain gauge sensors was invented by the Daeyomedi Company and the Korea Institute of Oriental Medicine^{37,61} to solve the problem of quantifying the exerted pressure, to record the three-dimensional waveform with pulse width information, and to detect the original PPW. Table 2 briefly presents the characteristics of the Bong-Kyo type and other commercial models.

2.4. Studies on physical quantification

Studies on the physical quantities of the PPW can be divided into two types: studies on the pulse diagnosis act and PPW written in the traditional medical classics, and studies from the hemodynamic point of view. The former seek to answer the question, “How can we reconstruct the Korean medical pulse diagnosis in a scientific and engineering-based way, and how can we interpret the definition of a PPW written in

Table 2 – Characteristics of pulse diagnostic device systems.

Device type	Bong-Kyo type	Hee-Soo type	Sord type	Daeyomedi type
Year	1968	1972	1986	2001
Sensor type	Piezoelectric sensor	Condenser microphone	Piezoelectric sensor	Piezoresistive strain gauge
Fixation	Band	Cuff	Clamp/finger	Robot arm
Pressure control	Impossible	Impossible	Impossible	Possible
Output waveform	Derivative PPW	Air vibration	Derivative PPW	Original PPW
PPW, pressure pulse waveform.				

the classics?” This question is closely related to the belief in Korean medicine that pulse diagnosis is an important holistic reflection of health and disease. Meanwhile, the latter answers the question, “What are the feature parameters of the PPW, and what is the cardiovascular meaning of these hemodynamic parameters?” The Korean medical meaning of pulse diagnosis is excluded from this type of study. PPW feature selection, aging or the physical quantity of blood pressure itself, hemodynamic study, and structural or functional disorders following the structural disorders of the heart are the main topics of study here.

Physical quantity studies for PPW structure analysis start with the literature reviews discussed in Section 2.2. Researchers have determined physical quantities from the classics through logic and specific established parameters,^{13,25,26,28,29,44,77-83} and have applied these parameters to signal-processing procedures. Studies of carotid-wrist pulse-taking,^{71,84} studies of rapid, slow, and moderate pulses based on the pulse-respiration ratio,^{24,74,85,86} studies of floating and sunken pulses,⁸⁷⁻⁹³ the string-like pulse,⁹⁴ and vacuous and replete pulses,^{95,96} correlation studies of expert diagnosis,⁹⁷ and studies on anatomical and hemodynamic PPWs⁹⁸ have been conducted.

The signal-processing technique or data-mining methodology has been applied to PPW feature selection studies.⁹⁹⁻¹⁰⁹ PPW analysis with Fourier transform^{110,111} and wavelet transform,^{112,113} and respiration rate extraction using fast Fourier transform¹¹⁴ have been conducted. Furthermore, statistical analysis of PPW parameters,¹¹⁵ neuro-fuzzy analysis,¹¹⁶ clinical studies on hypertension,¹¹⁷⁻¹¹⁹ studies on aging¹²⁰ and arteriosclerosis,¹²¹ and studies using modeling and simulation^{122,123} have been reported.

In addition, attempts have been made to match the extracted parameters with five-phase theory,^{101,102,106,109,124} but they have little validity from the Korean medical point of view.

2.5. Clinical studies

There is little evidence on the relationship between the PPW and disease except for written expressions in the traditional medical classics. Furthermore, because discussions have cited abstract expressions of the traditional medical classics repeatedly and in a circular fashion, pulse diagnosis should be clinically verified. Clinical trials have been continuously reported to confirm the clinical meaning of pulse diagnosis and analyze new diagnostic parameters. Clinical studies can be divided into four fields: the examination of healthy people, studies into examination of the constitution, the examination of specific diseases, and application as the

evaluation index after Korean medical treatments. PPW variations according to sex,¹²⁵ age,¹²⁶⁻¹³² body mass index,¹³³⁻¹³⁵ sensing sites,¹³⁶ and meals¹³⁷⁻¹⁴⁰ have been reported. Studies related to the Sasang constitution theory include characteristics studies¹⁴¹⁻¹⁴⁶ and constitution diagnostics studies.¹⁴⁷⁻¹⁴⁹

Various clinical trials on specific diseases have been performed, but they were mainly PPG¹⁵⁰⁻¹⁵⁹ or PWV¹⁶⁰⁻¹⁶⁴ studies. Apart from those studies, clinical trials have been performed in the areas of stroke,¹⁶⁵ hypertension,^{117,144,166,167} arrhythmia,¹³⁸ respiratory symptoms,^{168,169} sterility,^{170,171} diabetes mellitus,¹⁷² digestive symptoms,^{173,174} atopic dermatitis,¹⁷⁵ metabolic syndrome,¹³¹ and thyroid disorders.⁸⁵ PPW parameters have been used to evaluate the effect of Korean treatments, for example normal acupuncture,¹⁷⁶⁻¹⁷⁸ bee venom pharmacopuncture,¹⁷⁹ and wild ginseng pharmacopuncture.¹⁸⁰ In addition, agreement between interpretations,¹⁸¹ correlation between red blood cell volume and PPW,¹⁸² blood characteristics,¹⁸³ and PPW measuring sites^{184,185} have all been studied.

Almost all clinical studies have focused on the physical parameters of PPW and not on the pulse phase (e.g., floating pulse or sunken pulse) itself. In addition, statistical looseness and incorrect methodologies were the weak points of the previous clinical studies. Study groups were limited to the Korea Institute of Oriental Medicine, Kyung Hee University, and Dong-Eui University, showing that wide and varied clinical studies have not been conducted.

2.6. U-health systems

U-health is the convergence of ubiquitous computing techniques and medical services. It is defined as a remote service that can collect, process, transmit, and manage various pieces of information from customers without spatiotemporal limitations. Nowadays, many people want not hospital services requiring daily visits, but real-time care and advice services that can check various symptoms and measure biosignals automatically; in an aging society, people focus more on health management and disease prevention than on curing disease. Moreover, with the development of network, computing, and microelectromechanical system technologies, the demands for and expectations from U-health have increased rapidly.

In the field of pulse diagnosis, system research has been combined with the U-health service.^{108,186,187} In the U-health system, accessibility, convenience, and fast measurement are important issues. Thus, many PPG studies have been conducted using the wristband form¹⁸⁸ or fingertip probe form.¹⁸⁹⁻¹⁹¹ In this case, however, the PPG signal, the volume pulse waveform at the fingertip, is different from that from wrist PPW diagnosis, so additional analysis should be

performed. Database management systems to manage the measured information^{192–194} and the ontology of the measured PPW¹⁹⁵ have also been studied.

3. Technical challenges and strategies to overcome them

In this section, we discuss the technical challenges for improving the reliability, validity, and utilization of pulse diagnostic devices based on the previous studies reviewed above.

3.1. Sensors and actuators

As noted previously, skin contact, fixation, and pressure control are problems related to reliability and validity. Many methods have been developed, but no system can measure the PPW at the three palpation sites—*chon*, *guan*, and *cheok*—simultaneously with controlling the pressure exerted. To be able to realize traditional Korean medical pulse diagnosis, these technical issues need to be solved. Solutions can involve the research and development of a robotic arm or air pressure control system combined with multichannel piezoelectric films, conductive textiles,^{33,196} or array sensors.^{37,61,197}

3.2. Physical quantity studies

Physical quantity study is closely related to the content validity of pulse diagnostic devices. Misunderstandings of a PPG as a PPW, or a condenser microphone output as a pressure signal, have been naively accepted without definite verification. Thus, correct physical parameter measurements with the appropriate sensor technology should be developed, closely observing the approach of traditional Korean medical pulse diagnosis.

Some sensors detect the derivative PPW rather than the original PPW. Thus, because the PPW means the original PPW, research on derivative PPWs need additional discussion.

3.3. U-Health systems

U-health, which is based on wireless sensor networks, big data analysis, and high-speed computing technology, is a major issue for modern medical service and a blue ocean in market terms. Carrier vendors and the manufacturing industry intend to increase their U-health market share with their services, and many U-health service providers recognize healthy and subhealthy people as their sales target. Thus, for U-health pulse diagnostic devices, we must determine parameters that correctly indicate health status, examine the technical merits of measuring various kinds of data in short amounts of time, and facilitate high levels of accessibility with a portable or wearable form user interface.

Pulse diagnosis is a holistic diagnostic method in Korean medicine. If it is integrated with other biosignal information, we can better understand the patient's health status and expand the applicability of Korean medical treatment with regard to U-health.

3.4. Clinical study issues

About 40 years have passed since the first pulse diagnostic device was invented, but the problem of insufficient reliability and validity remains unsolved. Additionally, the history of clinical study in Korean medicine is not very long. Therefore, there are limitations to the high evidence level seen in clinical studies, and few clinical studies have been well designed either statistically and methodologically. Statistical and clinical applications should be understood deeply and analyzed carefully. Correlation between PPW parameters and clinical symptoms or diseases is usually misunderstood as causality.

A diagnostic device can be verified only after well-designed clinical studies have been conducted. We expect many hospitals or clinical research centers to perform proper clinical trials with the development of these devices themselves.

4. Conclusion

We have reviewed previous studies on pulse diagnostic device research and development according to various fields of study, and have discussed some issues related to the further development of pulse diagnostic devices that need resolving. Pulse diagnosis is a distinct and holistic method for gathering health information from patients in Korean medicine. It plays a critical role in differential diagnosis and in evaluation of the treatment effect. As the objectification and quantification of data- and evidence-based medicine are areas that are currently strongly emphasized, an appropriate pulse diagnostic device that reflects the approach of Korean medical will be helpful to accomplish the globalization and rationalization of Korean medicine. We hope that this review will stimulate more technical research and development and be a useful guide for realizing this goal.

Conflicts of interest

All contributing authors declare no conflict of interest.

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